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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/750,424	12/28/2000	Adrian Auf Der Maur	27656/37021	7858

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EXAMINER	
WESSENDORF, TERESA D	

ART UNIT	PAPER NUMBER
1639	

DATE MAILED: 06/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/750,424	DER MAUR ET AL.	
	Examiner	Art Unit	
	T. D. Wessendorf	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 February 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31 and 33-44* is/are pending in the application.

4a) Of the above claim(s) *1-30 and 39-41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *31,33-38 and 42-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-31 and 33-44 are pending.

Claims 1-30 and 39-41 are withdrawn consideration as being drawn to non-elected claims.

Claim 32 has been cancelled

Claims 31, 33-38 and 42-44 are under examination.

Specification

The objection to the disclosure because of the incomplete sentence at page 1, last paragraph has been obviated with the amendment to the specification.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31, 33-38 and 42-44, as amended, are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art

that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The as-filed specification does not provide support for the claimed method that is antigen independent. Applicants point out support at page 13, lines 13-30. Also the method step of "***providing*** suitable host cells ***harboring*** a nucleic acid library..... harboring a marker gene." A review of the cited section does not reveal support for said "antigen independent" method.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31, 33-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for reasons set forth in the last Office action.

In view of the amendments to the claims and in part of applicants' arguments, the rejection under paragraphs A-E no longer applies.

However, claims 35-38 and 42, as amended, are rejected as follows:

1. The term "harboring" in claim 35, for example, is indefinite as to whether the host cell inherently contain said nucleic acid library. Said term is not an art-recognized term within the context of the claim. The term "transformed or transfected" is suggested. Also, the "providing" step is unclear as to whether it is made or commercially supplied.

2. Claim 36 is unclear as to how the host cells can produced a first protein and a second protein from the same (?) library. The arbitrary designation of the relative terms first and second is confusing, as applied to the expression step. It is not clear how a first protein is determined and differentiated from the second protein when expressed by the same host cell, absence any structural distinction.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless -
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 31, 33-38 and 43-44, as amended, are rejected under 35 U.S.C. 102(a) as being anticipated by Worn et al (Jrnl. of Biological Chemistry) or Taliana et al (Jrnl. of Immunological Methods) for reasons of record.

Response to Arguments

Applicants argue that the subject matter of claims 36-38 and 42 differs from the cited prior art in that the interaction between the library encoded protein (comprising the intrabody) and the second fusion protein is mediated via a constant region of the library encoded protein. Specifically, the interaction of the two proteins does not involve the CDR region of the intrabody. (See figure 1) Therefore, the two proteins interact with each other in an antigen independent manner.

In response, applicants' argument, at least with respect to at least claims 31 and 33-35 are not commensurate in scope with the claims, which does no recite an interaction between two proteins. Notwithstanding this, Worn discloses said fusion of two proteins interacting via the regions in the scFv. Worn as recognized by applicants describes GNC4 that reacts with the scFv library. The argued reaction between the constant region

would be inherent to the teaching of Worn since the scFv inherently has this region.

See the response above for the arguments against the Taliana reference.

The rejection under Hoeffler no longer applies with the submission of the priority foreign application.

Claims 31 and 33-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Visintin et al (PNAS).

Response to Arguments

Applicants argue that Visintin et al relies upon the use of the two-hybrid system for the isolation of intrabodies wherein the identification of the intrabodies is based on the antigen dependent interaction between the antibody and its corresponding antigen.

In reply the argument under Worn is applied herein since applicants merely present the same argument.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over any one of Worn or Taliana or Visintin above in view of Ptashne et al (20040014036).

Each of Worn or Taliana or Visintin does not disclose the use Gal4 and Gal11P in their method. However, Ptashne at paragraph discloses the new transcription activator Gal4 and Gal111P. Ptashne discloses at [0007]-[0008] that transcriptional activators activate transcription by a novel mechanism as they do not squelch known activators when they are over expressed in yeast. Without wishing to be bound by any particular theory, we propose that these activators function by interacting with a component of the RNA polymerase II holoenzyme; this hypothesis is consistent with the observation that the only other transcriptional activator known not to squelch is Gall 1, which is part of the holoenzyme. The systems described herein utilize holoenzyme components, or factors that interact therewith, in a way that provides advantages over known transcriptional activation systems. For example, the protein-protein interaction systems that utilize Gal11 and/or Gal1P overcome some of

difficulties known in the art with standard di-hybrid and interaction trap systems. It would have been obvious to one having ordinary skill in the art at the time the invention was made to use Gal 4 and Gal11P in the method of each of Worn or Taliana or Vinsintin as taught by Ptashne. The advantages provided by Ptashne in the use of said Gal4 and Gal11P would provide the motivation to one skill in the art to replace the known transcription activators.

No claim is allowed.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

This application contains claims 1-30 and 39-41 drawn to a non-elected invention. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to T. D. Wessendorf whose telephone number is(571)272-0812. The examiner can normally be reached on Flexitime.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on (571)272-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

T. D. Wessendorf
Primary Examiner
Art Unit 1639

Tdw
May 29, 2004